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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,217	06/18/2004	Kathryn E. Urich	1435.008US1	4308

7590 09/19/2005

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EXAMINER

BOYKIN, TERRESSA M

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,217

Applicant(s)

UHRICH, KATHRYN E.

Examiner

Terressa M. Boykin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 9-26-03;3-8-00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

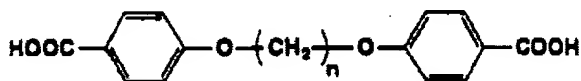
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

I. Applicant's arguments filed 6-29-05 have been fully considered but they are not persuasive.

In response to Applicant's argument that the reference(s) does, do, not contain the each and every element on which the Applicant relies, those limitations are either not stated in the claims and/ or are considered inherent.

The preferred aromatic dicarboxylic acid is represented in the following formula:



(As well as figures 1-2 of the reference.)

Note carefully that the $[O-(CH_2)-O]$ may read on the R moiety of applicants claimed invention, i.e. a difunctional moiety.

Thus, the references discloses aromatic polyanhydrides prepared from the same components as claimed by applicants as well as those employed for therapeutic use therein. Note that applicants arguments, although pertinent are not fully set forth in the claims. are so broadly defined, the reference may be interpreted as anticipating the claims while remaining within the scope of the invention as set forth in the specification. Thus, in view of the above, there appears to be no significant difference between the reference(s) and that which is claimed by

applicant(s). Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

Claim Rejections - 35 USC § 102

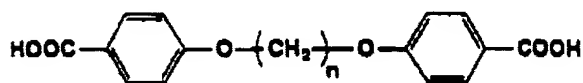
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10- 26 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0580386 see pages 2-9, Tables 1-3, and examples and claims 1-10.

EP 0580386 discloses an improved process for preparing an aromatic polyanhydrides is disclosed. The preferred aromatic dicarboxylic acid is represented in the following formula:



(As well as figures 1-2 of the reference.)

As noted above, the [O-(CH₂)-O] may read on the R moiety of applicants claimed invention....i.e a difunctional moiety.

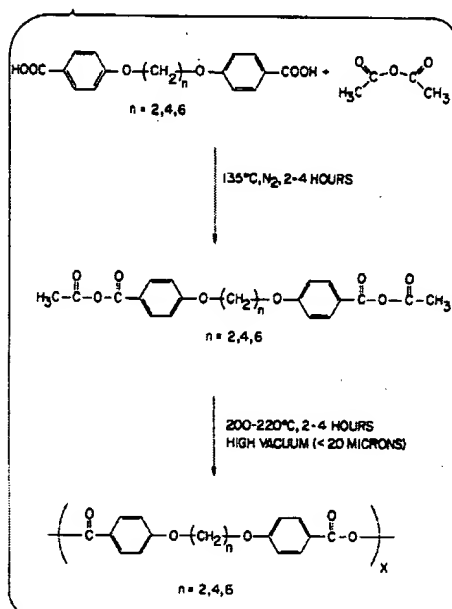
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With regard to claims 10, 11, 12, 13 –17 note beginning on page 5 line 46 that the polyanhydrides of the reference may be injected or molded to make implantable medical devices, especially wound closure devices. Further, with regard to applicant's claims regarding drug delivery, note claims 10 of the reference.

With regard to claim 18 note that reference discloses that "it should be apparent that block copolymers or blends with other absorbable or nonabsorbable polymer could be prepared."

With regard to claims 19 - 26, the reference discloses in Figure 2:

FIG-2



wherein the second prepolymer anticipates the formula of applicants' claim 19 and the limitations therein.

Claims 27 –40 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 61186309 see abstract, and claims.

With regard to claims 27 – 40 note that JP 61186309 discloses a composition for

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treating inflammation which includes a layer of maleic anhydride. The composition comprises a layer (I) and a layer (II). Layer (I) comprises (a) one or more polymer components of polyvinyl pyrrolidone, polyvinyl alcohol, alginic acid and its pharmaceutically acceptable salts, and a copolymer of maleic anhydride and methylvinyl ether, (b) an enzyme for tooth dirt, (c) a forming (sic) material, and (d) opt. other additives. The polymer components are 20-50 wt.% of total composition. of (I).

Layer (II) comprises (A) one or more of polyvinyl pyrrolidone, polyvinyl alcohol, alginic acid and its pharmaceutically acceptable salts, and a copolymer of maleic anhydride and methylvinylether, (B) one or more polymers of polyacrylic acid and its pharmaceutically acceptable salts, (C) an enzyme for tooth dirt, and (D) a forming (sic) material and other additives. The weight ratio of (A) and (B) is 70:30-95:5.

The enzyme includes dextranase, mutanase, etc. (C) includes starch, crystalline cellulose, dextrin, lactose, mannitol, sorbitol, etc.

Thus, as stated above, the references discloses aromatic polyanhydrides prepared from the same components as claimed by applicants as well as those employed for therapeutic use therein. Thus, in view of the above, there appears to be no significant difference between the reference(s) and that which is claimed by applicant(s). Any differences not specifically mentioned appear to be conventional. Consequently, the claimed invention cannot be deemed as novel and accordingly is unpatentable.

35 USC 112, Second Paragraph

Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substituted", without further definition, is considered bone non-enabling and indefinite.

The instant application provides no express statement or description in the specification to teach on of ordinary skilled in the art that all substituents, organic and /or inorganic, are properly within the subject matter applicants consider to be the invention. There is no explicit description of this vast terminology nor sufficient representative examples which may provide a basis for such terminology to satisfy the description requirements of the first paragraph of 35 USC 112. Although applicants may argue that the claims are inclusive of all substituents that would be suitable, there are no guidelines set forth as to which of the countless substituents are included.

Further, the term is not precise nor so defined as to provide clear cut indication of the scope of the subject matter intended to be with the scope of the claims.

Note that the term " substituted" is proper when modifying a chemical group: 1. if the term is defined or 2. if guidelines are present in the specification or 3. if sufficient examples are given so on of ordinary skill in the art could determine what substituents may be used. Note In re Conley, 490 F. 2d 972, 180 USPQ 454; In re Sus et al., 134 USPQ 301.

Correspondence

Please note that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

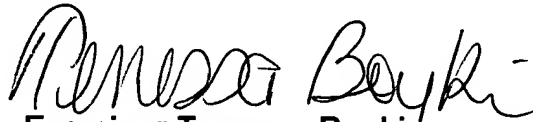
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Terressa Boykin whose telephone number is 571 272-1069. The examiner can normally be reached on Monday through Friday from 6:30am to 3:00pm.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. The general information number for listings of personnel is (571-272-1700).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmb


Examiner Terressa Boykin
Primary Examiner
Art Unit 1711